

REMARKS

This communication is in response to the final office action mailed on August 6, 2010 rejecting claims 1-15.

With this response, claim 15 is cancelled, claims 16-18 are newly presented, and claims 1 and 5 are amended under 37 C.F.R. § 1.114. Claims 1-14 and 16-18 remain pending in the application.

Claim rejections under 35 U.S.C. § 112, First Paragraph

Claims 1-15 were rejected under 35 U.S.C. § 112, first paragraph. The Examiner takes the position at page 3 of the final office action that the recitation in previously presented claim 1 of the vapor permeability of the patch being greater than 500 g/m² introduces new matter.

The applicant's representative respectfully notes for the record that the application as filed, for example in the specification filed on May 30, 2006, teaches at page 3, lines 17-30 that the vapor permeability of the patch is 200-2000 g/m².

With this response, independent claim 1 has been amended to remove the limitation on vapor permeability and claim 5 has been amended to recite the vapor permeability that was claimed when the application was filed.

Thus, it is respectfully requested that the rejections to claims 1-15 under 35 U.S.C. § 112 be withdrawn.

Claim rejections under 35 U.S.C. § 103

Claims 1-5, 8-11, 14, and 15 were rejected under 35 U.S.C. § 103 as unpatentable over Yamamoto, JP 10-033655 -machine translation- ("Yamamoto").

With reference to the machine translation of Yamamoto, Yamamoto discloses in the first paragraph of page 1 a pasting material for treating dermatitis that includes an adhesive layer for attachment to skin. Yamamoto discloses at page 2, paragraph 0009 that the problem to be solved includes the external use of the pasting material to treat atopic dermatitis. Yamamoto discloses at paragraph 0025 that since the pasting material of his invention is applied to inflamed skin that it is preferred to provide the pasting material with a size of about 15-600 cm². In particular,

Yamamoto discloses between paragraphs 0037-0042 the evaluation of his pasting material in which the pasting material was applied to the back skin of Homo sapiens or onto guinea pigs after their skin was shaved.

With this response, independent claim 1 has been amended to require the area of the patch is less than 5 cm² and the patch provides a wear time of at least four hours when adhered to mucosa of a user.

Support for the language of amended independent claim 1 is located in the application as filed (See the Specification filed on May 30, 2006) at least at page 3, lines 9-10; page 5, lines 1-7; page 7, lines 18-22; page 10, lines 25-28; and Examples 2 and 3 beginning at page 16, line 3.

The instant application teaches at page 2, lines 11-15 that adhesive patches applied to lips are exposed to large movements, stretching, friction, and high humidity and that all of these factors can contribute reducing the wear time of the patch.

Yamamoto discloses applying a pasting material to the external skin. Yamamoto does not teach or suggest an adhesive patch for application to mucosa of a user. Yamamoto does not teach or suggest a patch having a wear time of at least four hours when adhered to mucosa of a user. Those of skill in the art recognize that adhesion to dry skin (as disclosed by Yamamoto) is very different from applying adhesive to mucosa, as provided by the patch of independent claim 1.

Recently, the Supreme Court offered guidance on how references should be viewed when conducting an obviousness determination. The Supreme Court's position is: "A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1731; 82 USPQ2d 1385, 1389 (*emphasis added*). In making this point, the Court noted that "[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1738; 82 USPQ2d 1385, 1396 (*emphasis added*). In this regard, Yamamoto is directed to pasting material that is applied to external skin and does not teach or suggest or even acknowledge the notion of applying adhesive patch to mucosa. In fact, Yamamoto is silent in regard to the particle size of the particles of the adhesive layer which

suggests that neither Yamamoto nor one of ordinary skill in the art would arrive at adhesive patch for attachment to mucosa in light of the Yamamoto disclosure.

In addition, the pasting material of Yamamoto is applied to external skin (on the back or on skin after it is shaved) such that Yamamoto teaches away from a patch for application to mucosa. “[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious.” *KSR Int’l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1737; 82 USPQ2d 1385, 1395 (citing to *United States v. Adams*, 383 U.S. 39, 51-52; 148 USPQ 479).

Claim 5 has been amended to recite the same range of vapor permeability as claimed when the application was originally filed (See the claims as filed on May 30, 2006).

Claim 16 is newly presented to recite that the patch has a maximum thickness and a peripheral edge thickness of the patch does not exceed about 30% of the maximum thickness of the patch, the peripheral edge thickness configured to increase wear time of the patch by reducing rolling-up of a periphery of the patch away from the mucosa. Support for the language of claim 16 is located in the application as filed at least at page 6, lines 9-17 and at page 8, lines 5-17.

Claim 17 is newly presented to recite that an outer periphery of the patch is bevelled between the maximum thickness of the patch and the peripheral edge thickness. Support for the language of claim 17 is located in the application as filed at least at page 8, lines 5-17.

Claim 18 is newly presented to recite that the patch is a herpes patch configured to provide a discreet appearance in which the bevelled outer periphery of the patch smoothly transitions to the anatomical surface. Claim 18 depends from claim 17 and support for the language of claim 18 is located in the application as filed at least at those locations identified above for claim 17 and at page 10, lines 25-28 and in Examples 2 and 3 beginning at page 16, line 3.

Based on all of the above, it is believed that amended independent claim 1 recites patentable subject matter and is not rendered obvious under section 103 over the cited references.

Claims 6 and 7 were rejected under 35 U.S.C. § 13 as unpatentable over Yamamoto in view of Udagawa, JP 06199660 (“Udagawa”). The Examiner concedes at page 8 that Yamamoto

is silent as regards the particle size of the hydrochloride particles. Udagawa is cited as providing cellulose particles have a size range of 1-150 micrometers.

Yamamoto's failure to disclose or teach the particle size of the hydrochloride particles further validates the arguments above that the pasting material of Yamamoto is not suitable for application to mucosa.

In any regard, Udagawa fails to cure the deficiencies of Yamamoto in establishing a *prima facie* case of obviousness under section 103. It is believed that amended independent claim 1 is nonobvious under section 103 such that dependent claims 6 and 7 are also nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Claims 12 and 13 were rejected under 35 U.S.C. § 103 as unpatentable over Yamamoto and further in view of Hirsch, U.S. Pat. No. 3,650,065 ("Hirsch"). The Examiner concedes at page 9 that Yamamoto does not teach a patch having an absorbent pad or a pad with one or more cavities. Hirsch is cited as disclosing a bandage with a reservoir for storing fluid. Consequently, Hirsch fails to cure the deficiencies of Yamamoto in establishing a *prima facie* case of obviousness under section 103. It is believed that amended independent claim 1 is nonobvious under section 103 such that dependent claims 12 and 13 are also nonobvious.

CONCLUSION

Applicant respectfully asserts that pending claims 1-14 and 16-18 recite patentable subject matter and are in condition for allowance.

The Examiner is respectfully urged to telephone the undersigned if issues remain outstanding.

The office is authorized to charge any fees actually due and credit any overpayment to deposit account 50-4439.

Respectfully submitted,

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